

Brian Schweitzer
Governor



Ron de Yong
Director

Date: December 28, 2007
To: Interested Parties
From: Ron de Yong, Director
Re: Camelina

This is an exciting time not only for the bio-fuels industry but also for our agriculture producers, ag-related businesses and ultimately for our rural communities. The potential for developing camelina as a major crop in Montana is real, with a diverse range of products, uses and marketing opportunities.

The Montana Department of Agriculture is committed to working cooperatively with all the players to move the camelina effort forward from the research phase to the commercial phase. Governor Schweitzer and the department believe that oilseed crops are a good fit for Montana. It appears that the era of cheap energy is over, and crops can compete in helping to fill the nation's energy needs. How to do this most efficiently will require experimentation and some risk taking by growers and businesses seeking new opportunities in Montana. Camelina and other oilseeds are well suited to small scale production of bio-fuels because biodiesel can be produced in facilities of varying sizes, from on-farm production to industrial-size plants.

Producing any new crop requires research in agronomic management, crop breeding for regional conditions and end-use characteristics, and experimentation for EPA-registered pesticides. The commercial phase requires data submission and approval from the agencies that regulate fuel and product standards, as well as federal acceptance of research data regarding safety and nutrition before the oil or byproducts can be marketed as ingredients in food or livestock feed. Private companies and Montana State University (MSU) are partners in these efforts.

It is the department's intent to be a source of current and accurate information regarding the status of various issues surrounding camelina, and to identify the best person to contact for additional information. Attached is the latest overview on regulatory issues. Updates will be Agricultural Sciences Division Administrator at (406) 444-2944 or garnes@mt.gov with any questions, comments or concerns.

We hope this information will help to ensure the appropriate development of camelina, so we can see it grow to be a successful crop in Montana. Working together, we can keep Montana moving forward.

EXECUTIVE SUMMARY

Camelina is potentially a beneficial crop for Montana producers and processors. Several issues must be resolved in order to realize camelina's full commercial value. The Montana Department of Agriculture (department) will work with those interested in camelina to achieve success. Among the issues, and the current status of each, are:

Commodity Dealer / Warehouse Licensing (pages 3-4)

Companies and individuals that hold commodity dealer licenses may purchase camelina from producers. The department is required to license any company that annually buys more than \$30,000 of grain or oilseed commodities from Montana producers. Licensed companies must be bonded, which helps to ensure the stability of the company buying and storing commodities and provides some protection to producers. No license is required to buy oilseeds from other licensed commodity dealers.

Feed Ingredient Uses (pages 4-6)

Private companies, in cooperation with Montana State University and other universities, have conducted some animal feeding trials with camelina. At present, the federal Food and Drug Administration (FDA) has not approved camelina or its byproducts as a commercial feed ingredient. The department's feed program ensures that only safe and approved feeds are provided for animal consumption. Private efforts to gain FDA approval for the unrestricted use of camelina as a feed ingredient will require additional research to be submitted.

Seed Labeling and Licensing (pages 7-8)

Properly labeled and approved camelina seed varieties may be sold by licensed dealers. The department's seed program assures farmers, gardeners, and homeowners that seeds offered for sale in Montana are truthfully labeled for identity, contamination, and viability. The program encompasses license requirements, label requirements, seed dealer inspections and seed sampling.

Seed Pressings as Fertilizer (pages 8-9)

Byproducts from agricultural commodities are sometimes sold for use as fertilizers or soil amendments or as ingredients in such products. The department's fertilizer program ensures that only quality fertilizer products are sold in Montana for consumer protection. The department conducts inspections, sampling and analysis, and reviews labels of products manufactured, sold or distributed in Montana to monitor compliance with the fertilizer law. A license is required to distribute fertilizer products, and products must be registered.

Organic Certification (page 9)

Camelina can be certified as organic using the same standards and procedures required of other crops. The department provides certification to organic producers and handlers under standards which include requirements for diverse crop rotations to maintain soil organic matter; manage weeds, pests and crop diseases; manage soil fertility and plant nutrition; and control soil erosion. Certified organic products and commodities must also comply with other regulatory requirements including those mentioned elsewhere in this summary.

Montana Pesticide Program (pages 9-10)

The program ensures the safe use of pesticides in Montana. Because camelina is such a new crop, there are currently no Environmental Protection Agency (EPA) approved chemical

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pesticides for the crop. A request has been made to EPA to approve the use of sethoxydim (Poast) on camelina, but that decision will probably not be made until September 13, 2008.

Federal Commodity Standards and Crop Insurance (pages 10-11)

Currently, there is no Federal Grain Inspection Service (FGIS) standard for camelina, nor is there federal crop insurance available for camelina producers. U.S. Senator Jon Tester's office has been working to include language in the 2007 Farm Bill. Camelina would not be eligible for federal crop insurance payments until FGIS standards are developed.

Foreign Standards (pages 12-13)

In European feed law, camelina is listed as an "undesirable substance" and cannot be included in commercial feeds above "trace amounts not quantitatively determinable."

In Canada, camelina meal cannot be commercially marketed as an animal feed ingredient. The seed may be acceptable in Canadian feeds at very low levels because it is considered a weed.

Biodiesel Standards (pages 13-15)

Fuel producers have the liability and responsibility to ensure and prove that a biodiesel product meets federal standards, known as American Standard Testing Method (ASTM) D6751, as well as any future specifications and sulfur content.

Introduction

Camelina has been around for centuries, however, there are some issues to be considered and resolved before the production and distribution of camelina products can be pursued commercially. Many of the issues revolve around the compliance of regulations within the industries involved. There are currently many entities working on camelina in a research mode. As the research moves forward, the department wants to be a part of the success of this new crop in Montana.

Commodity Dealer / Warehouse Licensing

Title 80, Chapter 4, Montana Code Annotated (MCA)

1. Relevant definitions: (80-4-402, MCA)

- "Commodity Dealer" means a person who engages in a business involving or, as part of the business, participates in buying, exchanging, negotiating, or soliciting the sale, resale, exchange, bailment, or transfer of any agricultural commodity in the state of Montana.
 - (b) The term does not include:
 - (i) a person engaged solely in storing, shipping, or handling agricultural commodities for hire;
 - (ii) a person who buys agricultural commodities from a licensed commodity dealer;
 - (iii) a person who does not purchase more than \$30,000 worth of agricultural commodities from producers during a licensing year; however, once a person exceeds the \$30,000 exemption, the person shall obtain a license and is not eligible for the exemption for the succeeding year;
 - (iv) a person who is the producer of agricultural commodities that the person actually plants, nurtures, and harvests;
 - (v) a person whose trading in agricultural commodities is limited to trading in commodity futures on a recognized futures exchange; or
 - (vi) a person who buys agricultural commodities used exclusively for the feeding of livestock and not for resale.
- "Public warehouse" or "warehouse" means an elevator, mill, warehouse, sub-terminal grain warehouse, public warehouse, or other structure or facility in which, for compensation, agricultural commodities are received for storage, handling, processing, or shipment. The term includes facilities that commingle commodities belonging to different lots of agricultural commodities.

2. Regulatory requirements:

- The annual licensing fee for each person engaged in the business of a commodity dealer or a commodity warehouse is \$464 per location. (Administrative Rules of Montana (ARM) 4.12.1024)
- Bonding Requirements – The minimum bond requirement is \$20,000 per type of license. Additional bonding may be required depending on the value of agricultural commodities purchased, the storage capacity of the warehouse, and/or the financial stability of the company. (Title 80, Chapter 4, MCA)

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3. **Considerations:**

- Any company that is purchasing camelina grain in excess of \$30,000 from producers are to be licensed and bonded as a commodity dealer.
- To the department's knowledge, all companies purchasing more than \$30,000 worth of camelina grain from producers are licensed and bonded.

Feed Ingredient Uses

Title 80, Chapter 9, Montana Code Annotated (MCA)

1. **Relevant definitions:** (80-9-101, MCA)

- "Commercial feed" means all materials or combinations of materials that are distributed or intended for distribution for use as feed or for mixing in feed, unless the materials are specifically excluded by law.
- "Distribute" means to offer for sale, sell, exchange, or barter commercial feed or to supply, furnish, or otherwise provide commercial feed to a contract feeder.
- "Distributor" means a person who distributes commercial feed.
- "Feed ingredient" means each of the constituent materials making up a commercial feed or a noncommercial feed.

2. **Regulatory requirements:**

- A separate license is required for each facility that manufactures commercial feed within this state or for each facility that distributes commercial feed in or into this state. (80-9-201, MCA)
- All commercial feeds must be labeled as required in 80-9-202, MCA and formatted as outlined in the 2000 Association of American Feed Control Officials (AAFCO) Model Regulations. Labeling cannot be false or misleading. (80-9-203, MCA)

The department has adopted, by reference, the AAFCO Model Regulations. Thereby, recognizing the feed ingredient definitions listed in the AAFCO Official Publication as the official list of approved feed ingredients for the state of Montana. (Administrative Rules of Montana (ARM) 4.12.219)

Feed or feed ingredients/additives that are not listed or recognized as approved by the state, AAFCO, or FDA are thereby considered not approved. The lists and references of such feed ingredients are contained in:

- the AAFCO Official Publication;
- 21 CFR 558 – New animal drugs for use in animal feeds;
- 21 CFR 573 – Food additives permitted in feed and drinking water of animals;
- 21 CFR 580 – Substances generally recognized as safe (GRAS); and
- 21 CFR 584 – Food substances affirmed as generally recognized as safe in feed and drinking water of animals.

* The above lists have been adopted by reference into the Montana Commercial Feed Act within Administrative Rules of Montana 4.12.221.

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Feed Ingredient Submissions Summary

The Association of American Feed Control Officials (AAFCO) is composed of state, federal, and international regulatory officials who are responsible for the enforcement of state laws regulating the safe production and labeling of animal feed, including pet food. FDA and AAFCO work together in the area of feed regulation, particularly in the establishment of definitions to describe new feed ingredients. Each year AAFCO publishes its Official Publication which includes a model feed bill for states to adopt in regulating feed products and a list of accepted feed ingredients. Most states have adopted all or part of the model feed bill and allow feed ingredients listed in the publication to be used in their respective territories.

AAFCO Ingredient Definition - This process is described in the AAFCO Official Publication (p. 251 in the 2007 official publication). The ingredient sponsor works with the AAFCO Investigator to submit a package of information about a proposed ingredient to the Food & Drug Administration (FDA) for review. The review principally establishes the safety of the product, usually for a specific use. Product effectiveness for the proposed use and manufacturing chemistry are also addressed. Upon favorable completion of the review, FDA often issues a “regulatory discretion letter”, saying that FDA does not anticipate taking regulatory action against that ingredient in feed as long as safety problems do not develop and use of the ingredient stays within the limits established in the AAFCO ingredient definition.

However, if safety concerns are present, FDA requires a food additive petition from the ingredient sponsor. Approval of a proposed ingredient through this process will result in published regulations within the Code of Federal Regulations (CFR) before AAFCO can establish a definition.

General Recognition of Safety - A substance can be generally recognized as safe for a specific use in feed if there is consensus about its safety for that use among experts who are qualified by scientific training and experience to evaluate the ingredient. An ingredient cannot be GRAS for any and all uses, but is GRAS only for the use specifically identified in the GRAS determination. A GRAS determination consists of two parts, safety and common knowledge. The safety determination, which is done by qualified experts, can be based on 1) scientific procedures, i.e., the same quantity and quality of data/information needed to gain approval of a food additive petition or 2) common use of the ingredient in feed prior to 1958. The second part of a GRAS determination involves the general recognition element, i.e.; there is common knowledge about the ingredient in the scientific community knowledgeable about substances added to feed. The common knowledge elements require that the information used as the basis of a GRAS determination be in the public domain, i.e. is published. A GRAS determination cannot be solely based on private or proprietary information/data.

Food Additive Petition - This process is described in the Code of Federal Regulations (CFR), 21 CFR 571. Food additives currently permitted by FDA in the food or drinking water of animals are listed in 21 CFR 573. These ingredients may only be used within the scope of the applicable regulation. Most, but not all, of

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these additives are listed in the Official Publication in section 87, Special Purpose Products.

Any substance intentionally added to an animal feed, including pet food, must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use. The basis of a food additive regulation is an approved food additive petition. The food additive petition should include an adequate factual basis to establish that the food additive is safe for its intended use, under the conditions of use specified in the petition. If the petitioner meets this burden of proof, the food additive can be approved for use in animal feed.

There are several types of food additives based on its composition and intended use. A food additive generally provides one or more of the following, i.e., nutrient, aroma/flavor, taste, soluble or insoluble fiber, stabilizer, emulsifier, sequestrant, chemical preservative, anti-oxidant, anti-caking agent, etc.

Section 571 of Part 21 of the CFR prescribes the kinds of data that must be submitted by the petitioner and the format which the food additive petition must follow when sent to FDA. While the actual content may vary from petition to petition, depending primarily on the food additive's composition and intended use, each of the following subject areas must be addressed: human food safety, target animal safety, environmental impact, utility, labeling, proposed regulation, assay methodology, and manufacturing process and controls. Subsequently, when the FDA concludes that the available data for a food additive are sufficient to meet current criteria, the FDA issues a regulation permitting the petitioned use of the additive.

3. Considerations:

- The FDA received an application for the approval of camelina as a new feed ingredient in July 2007.
- Camelina and its byproducts are not officially defined as a feed ingredient by the Association of American Feed Control Officials (AAFCO).
- The Food and Drug Administration (FDA) has not approved camelina or its byproducts as a feed ingredient.
- No feed licenses have been issued by the Montana Department of Agriculture because camelina is not an approved feed ingredient at this time.
 - If or when camelina is awarded an approved feed ingredient status, each facility that manufactures or distributes the meal as a feed ingredient will be required to acquire a feed license unless they are currently licensed to distribute other commercial feed products.
- Any camelina meal or camelina by-products used as a feed ingredient in Montana must be identified and used only for terminal research purposes in pursuit of a FDA approved feed ingredient definition.
- It is unlawful to distribute into commerce animals (including processed animal products and animal by-products) that have been fed camelina meal or camelina by-products.

Seed Labeling and Licensing

Title 80, Chapter 5, Montana Code Annotated (MCA)

1. Relevant definitions: (80-5-120, MCA)

- “Seed dealer” means a person who sells seeds.
- “Seed labeler” means a person affixing labels to seeds, with that person's name, address, and other information as required in 80-5-123, MCA.
- “Seed conditioning plant” means a place of business, whether a permanent or portable facility, that conditions seeds.
- “Conditioning” means drying, cleaning, scarifying, and other operations that could change the purity or germination of a seed and require the seed lot to be retested to determine labeling.
- “Sell” means to offer for sale, expose for sale, have in possession for sale, exchange, barter, or trade. The term includes furnishing agricultural seed to growers for the production of a crop on contract.

2. Regulatory requirements:

- A license is required for (80-5-130, MCA):
 - Seed dealers selling seed.
 - Labelers whose names appear on seed labels.
 - Conditioners who clean seed to sell.
 - Licensed Montana producers who sell more than \$5,000 worth of seed.
- All containers of seed sold or offered for sale must be properly labeled (80-5-123, MCA).
- Alternative Dispute Resolution for seed performance failures (80-5-501, MCA).

3. Considerations:

Varieties

- Three varieties of camelina were developed through Montana State University:
 - MT301, MT303 and MT305 were the varieties developed.
 - MT303 was not approved for release.
- Each variety was originally requested to be released as Plant Variety Protection Act Title V varieties and, therefore, could only be sold as certified seed and controlled by the variety owner.
- However, two of the above mentioned varieties were approved for release through Montana State University in January of 2007.
 - Blaine Creek (MT301) and Suneson (MT305) were the varieties released.
 - Both varieties were public releases, meaning they could be sold by anyone and sold as common seed.
- A plant breeder is working on improvements to camelina.

Standards

- The Montana Seed Growers Association is drafting working documents for establishing standards for certified seed for camelina. It is anticipated that flax standards may be adapted to start with and that initial standards will have to be established by planting time of spring 2008 since the two MSU-released varieties of camelina will be made available to producers then. A major challenge for

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setting seed standards and inspecting camelina seed will involve inspecting for genetic purity and distinguishing weedy off-types of camelina from the actual variety of camelina. Tolerances have yet to be determined for weedy off-types of camelina and critical weed seeds. Concern has been communicated by the Central Montana Agriculture Research Center in Moccasin about weed seed content for lambsquarter and kochia.

- There are efforts in Nebraska to establish seed standards for camelina, and at least initially flax seed standards may be used there. It may be necessary to unify seed standards through the Association of Official Seed Certifying Agencies (AOSCA <http://www.aosca.org/>).
- It is anticipated that establishment of seed standards for camelina will be a moving target and that potentially multiple sets of standards will be necessary. It is also anticipated that in the future, there may be at least two sets of camelina varieties (bio-fuel types and food grade types).
- Typically, seed standards are developed separately from Federal Grain Inspection Service (FGIS) standards. There is potential opportunity for coordinated standards development.

Seed Pressings as Fertilizer

Title 80, Chapter 10, Montana Code Annotated (MCA)

1. Relevant Definitions: (80-10-101, MCA)

- "Commercial fertilizer" includes any substance containing one or more recognized plant nutrients which is used for its plant nutrient content and which is designed for use or claimed to have value in promoting plant growth, yield, or quality of the crop
- "Distribute" means to offer for sale, sell, barter, or otherwise supply commercial fertilizers.
- "Distributor" means any person who distributes.
- "Grade" means the percentages of total nitrogen, available phosphorus or phosphoric acid, and soluble potassium or soluble potash stated in whole numbers in the same terms, order, and percentages as in the guaranteed analysis.
- "Soil Amendment" means any material not included under commercial fertilizer or those products subject to the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, which is added to the soil or to plants for purposes of influencing the growth, yield, or quality of the crop, soil flora or fauna, or other soil characteristics.

2. Regulatory requirements:

- No person shall distribute in this state any type of fertilizer or soil amendment until a license to distribute has been obtained from the department for each facility distributing into this state and for each handling facility in this state. (80-10-202, MCA)
- Each brand and grade of fertilizer and each soil amendment must be registered by or on behalf of the manufacturer before distribution in this state.
- (80-10-201, MCA)

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- The department shall require the applicant to furnish replicated data, performed by a reputable investigator whose work is recognized as acceptable by the director of the agricultural experiment station or his designee, verifying any claims for effectiveness or agricultural value of any fertilizer that is not generally recognized as having the values claimed at the use rates recommended. (80-10-201, MCA)
- The plant nutrient content of every brand and grade of commercial fertilizer shall remain uniform for the period of registration. (80-10-203, MCA)
- Labeling (80-10-204, MCA)
 - Any commercial fertilizer distributed in this state in packages shall have affixed to or printed on the container a label
 - Any bin in the state in which commercial fertilizer is stored for distribution must have affixed to or printed on it a label
 - All commercial fertilizer delivered in this state in bulk, whether a manufactured grade or blended grade, shall be accompanied by a clearly legible document which shall be supplied to the purchaser at the time of delivery and at the time his invoice is delivered.
- Inspection and Sampling (80-10-206, MCA)
 - The department, in cooperation with the agricultural experiment station of Montana State University-Bozeman, shall sample, inspect, analyze, and test commercial fertilizers and soil amendments distributed in this state at a time and place and to an extent necessary to determine whether the commercial fertilizers or soil amendments are in compliance with this chapter. The department may enter upon any public or private premises during regular business hours in order to have access to commercial fertilizers or soil amendments subject to this chapter.

Organic Certification

Title 80, Chapter 11, Montana Code Annotated

Any producer or handler intending to sell, label or otherwise represent crops, feed or any other raw or processed agricultural product as "organic" must be certified by a USDA-accredited organic certification agent. The Montana Department of Agriculture is USDA accredited and can provide certification services to organic producers and handlers in Montana. Organic crop and livestock producers, feed processors and other organic product handlers are required to comply with other pertinent regulations, including those regarding the sale or use of camelina or camelina products as a feed ingredient.

Montana Pesticide Program

Title 80, Chapter 8, Montana Code Annotated (Enforcement of state and federal labeling requirements)

1. Relevant definitions:

- Pesticide registrants—the chemical company who registers the pesticide with the Environmental Protection Agency (EPA) and the state.
- IR-4 Project—The Western Region IR-4 project is housed at UC Davis, and the IR-4 project's mission is to provide safe and effective pest management solutions

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for specialty crop growers. IR-4's Montana representative is Dr. Mary Burrows, the Extension Plant Pathologist at Montana State University.

- Tolerances—a level of pesticide residue that is allowed to be on the crop. It is important that pesticide residues do not exceed the tolerance established for that particular crop because they are based on complex calculations that ensure human and animal health are protected from harm due to exposure to the pesticide through all uses of the pesticide. Tolerances are set using research and analytical data that includes application rates, efficacy and expected exposures from other sources. Generally, at least seven years of data is needed to develop a tolerance.
- Crop grouping—a group of similar crops that is identified by the Environmental Protection Agency (EPA). Tolerance data may be shared within a crop grouping.

2. Regulatory requirements:

- Either a pesticide registrant, or IR-4 with support from the registrant, may submit a petition to EPA requesting the use of a pesticide on camelina. The EPA must have appropriate data to support the development of a tolerance. In March 2007, EPA informally approved Crop Group 20, the oilseeds crop group. Camelina was included in the Canola sub-group of the oilseeds. This means that the data used to establish the tolerance for a pesticide on canola can be used to establish a tolerance for camelina.
- In addition to the setting of a tolerance, EPA also must evaluate the potential for the use of the chemical to impact the environment, as well as add the new use to the existing uses of the chemical, and determine if it is acceptable to increase that particular pesticide's use from a human and animal health standpoint.

3. Considerations:

- IR-4 has requested that EPA approve the use of sethoxydim (Poast) on camelina. That decision will be made by September 13, 2008, mandated by the Pesticide Registration Improvement Act.
- Two years of herbicide research has been completed at the Southern Research Center in Huntley, Montana.
- Pesticide registrants must support the request to use the product. In order for them to support the use, they must be sure that there are no concerns with phytotoxicity or efficacy. Most chemical companies say they need several years of research at several sites in the proposed growing area.
- Fungicides will likely be needed in the short term. Insecticides may also be needed as well.

Federal Commodity Standards and Crop Insurance

Federal Commodity Standards

On October 3, 2007, the United States Department of Agriculture (USDA) Farm Service Agency state office in Bozeman indicated that there had been no progress in establishing a Federal Grain Inspection Service (FGIS) number (standard) for camelina. Crops are not eligible for government payments until they have received a FGIS number. It is unknown what efforts had been undertaken to pursue a FGIS number for camelina (if any).

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Federal Crop Insurance

According to U.S. Senator Jon Tester's office, as of October 3, 2007, the following language was in the Farm Bill (Note: It is unknown whether changes have been made since that date, nor whether the provision will survive negotiations with the U.S. House of Representatives).

SEC. 1613. CAMELINA PILOT PROGRAM.

(a) In General.—Section 523 of the Federal Crop Insurance Act (7 U.S.C. 1523) is amended by adding at the end the following:

“(f) Camelina Pilot Program.—

“(1) IN GENERAL.—Beginning with the 2008 crop year, the Corporation shall establish a pilot program under which producers or processors of camelina may propose for approval by the Board policies or plans of insurance for camelina, in accordance with section 508(h).

“(2) DETERMINATION BY BOARD.—The Board shall approve a policy or plan of insurance proposed under paragraph (1) if, as determined by the Board, the policy or plan of insurance—

“(A) protects the interests of producers;

“(B) is actuarially sound; and

“(C) meets the requirements of this title.”.

(b) Noninsured Crop Assistance Program.—Section 196(a)(2) of the Federal Agriculture Improvement and Reform Act of 1996 (7 U.S.C. 7333(a)(2)) is amended by adding at the end the following:

“(D) CAMELINA.—

“(i) IN GENERAL.—For each of crop years 2008 through 2011, except as provided in clauses (ii) and (iii), the Secretary shall consider camelina to be an eligible crop for purposes of the noninsured crop disaster assistance program under this section.

“(ii) EXCEPTIONS.—For purposes of providing assistance for producers of camelina in accordance with clause (i)—

“(I) in calculating the payment under subsection (d)—

“(aa) the quantity specified in paragraph (1) of that subsection shall be considered to be not more than 75 percent, as determined by the Secretary; and

“(bb) the percentage of the average market price specified in paragraph (2)(B) of that subsection shall be considered to be not more than 75 percent, as determined by the Secretary; and

“(II) the Secretary shall increase the service fee described in subsection (k)(1) as the Secretary determines appropriate to reflect increased liability.

“(iii) LIMITATION.—Producers that are eligible to purchase camelina crop insurance, including camelina crop insurance under a pilot program, shall not be eligible for assistance under this section.”.

Foreign Standards

European Feed Prohibition

The agency that deals with feed regulations in the European Union is the European Food Safety Authority (EFSA), which began operating in 2002 (http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_home.htm).

The European Food Safety Authority was established by:

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 *“Laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety”*.

The legal requirements for animal feed business operators are spelled out in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 in Chapter II, Section 4, Article 20 “Responsibilities for feed: feed business operators”, which spells out that feed shall be destroyed if it does not meet feed safety requirements.

The Summaries of European Union Legislation on Animal Nutrition (Undesirable substances and products in animal feed <http://europa.eu/scadplus/leg/en/lvb/l12069.htm>) identifies Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 as the body of law that sets maximum levels for the presence of undesirable substances and products in animal feed put into circulation within the European Union. In Directive 2002/32/EC, Annex 1 provides a list of undesirable substances. Camelina sativa is listed as #31 in the list of undesirable substances; with a maximum content of “trace amounts not quantitatively determinable” (page 9 of 12 of the PDF file).

To view the full text of 2002/32/EC, the PDF file of the English version (EN) must be downloaded from the following website in order to view the list of undesirable substances (Annex 1 of 2002/32/EC).

http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=2002&nu_doc=32

Status of Camelina in Animal Feed in Canada

It appears that at the present time, camelina meal cannot be commercially marketed in Canada as an animal feed ingredient. The Canada Feed Act of 1983 lists animal feed ingredients that are permitted to be used without being registered in Part I of Schedule IV and Part I of Schedule V. Part I of Schedule IV includes a list of a vast number of feedstuffs, including canola oil and meal. The Canada Feed Act specifies in its Standards and General Requirements that a mixed feed shall not contain ingredients other than those listed in Schedule IV or V. Schedule IV and Schedule V do not include camelina, camelina meal, or camelina oil.

Because camelina feed products are not included in Schedule IV or V, camelina feed products would be considered novel feeds. “Novel feed” means a feed, comprising an organism or organisms, or parts or products thereof, that (a) is not set out in Schedule IV or V, or (b) has a novel trait. “Novel trait” means a characteristic of the feed that (a) has been intentionally selected, created or introduced into the feed through a specific genetic change,

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and (b) based on valid scientific rationale, is not substantially equivalent, in terms of its specific use and safety both for the environment and for human and animal health, to any characteristic of a similar feed that is set out in Schedule IV or V.

According to the Canadian Food Inspection Agency, this examination of the Canadian regulations indicates that camelina would have to go through the process of notification and authorization of the release of novel feeds.

The Canada Feed Act of 1983 describes the process for notification and authorization of the release of novel feeds. Canada Feed Act of 1983:
<http://laws.justice.gc.ca/en/showtdm/cr/SOR-83-593>

Part I of Schedule IV provides the standards for canola meal (5.3.3 and 5.3.4) and canola oil (4.5.3). Of interest in these specifications is the restriction on content of erucic acid and several types of glucosinolates in the oil and meal portion of canola. Since glucosinolate content is a concern for camelina, it would seem likely that glucosinolate analysis (and potentially plant breeding to alter glucosinolate content) would be prerequisite to the scientific study substantiating the safety of camelina oil and meal in the process of establishing camelina products as “novel feeds” or getting camelina products listed in Schedule IV.

In the Feed Act of 1983, *Camelina sativa* seed is listed as a weed, acceptable in feed only in prescribed tolerances.

19. (1) Subject to subsections (2) and (3), a feed shall not contain

(a) more than one-half of one per cent of the seeds of weeds listed in Table I of Schedule II except when screenings are sold or offered for sale singly, in which case the screenings may contain any amount not exceeding one per cent of such materials and an additional one per cent of wild mustard and hare's ear mustard seed;

(h) in the case of a feed that is chopped, crushed or ground, more than 15 viable seeds per 30 g of the weeds listed in Table 2 of Schedule II;

Camelina sativa seed is listed as a weed in:

- Schedule II, Table 1 Injurious weeds under paragraph 19(1)(a) Item #5
- Schedule II, Table 2 Weeds under paragraph 19(1)(h) Item #13

Biodiesel Standards

(Information provided by the Montana Department of Environmental Quality.
Contact: Howard Haines, (406) 841-5252 or hhaines@mt.gov)

Producers making biodiesel for sale in the United States must be certified by the Environmental Protection Agency (EPA) and the Internal Revenue Service (IRS). The pure (B100) biodiesel blend stock must meet specification ASTM D6751 before blending with petroleum diesel. This specification was developed using data from many feedstocks, and so the specification is feedstock neutral, meaning camelina can be used to produce biodiesel. Both federal and state agencies monitor and enforce different aspects of fuel standards. Care should be taken in the amount of sulfur or sulfantated products used in the production of the oilseed and fuel, as the biodiesel will need to meet EPA's ultra low sulfur specifications as with all fuels. Other Montana oilseed oils have been analyzed with higher-than-standards sulfur content. As with other fuel specifications, the fuel producers have the

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liability and responsibility to ensure and prove that the fuel meets ASTM D6751 and future specifications and sulfur content. All licenses, registrations, and standards are in place to make biodiesel from camelina oil.

1. Regulatory requirements, permits and other laws:

- To the extent a product is advertised as increasing gas mileage, reducing engine wear, or decreasing emissions the following Federal Trade Commission (FTC) guidelines must be followed.
<http://www.ftc.gov/bcp/edu/pubs/consumer/autos/aut10.shtm>
<http://www.ftc.gov/opa/2002/04/energysurfletter.shtm>
Contact person, Cort Jensen, Attorney, Montana Department of Agriculture, (406) 444-5402, cojensen@mt.gov.
- Biodiesel Production or Use and Sale:
 - Alternate Fuel Refueling Property Tax Credit, Internal Revenue Service (IRS)
 - Biodiesel Blending and Storage Tank Credit, Montana Department of Revenue (DOR)
 - Biodiesel Fuel Registration with Environmental Protection Agency (EPA), Jim Caldwell, (202) 343-9303, caldwell.jim@epa.gov
 - Biodiesel Fuel Registration with the Internal Revenue Service (IRS) Form 637, <http://www.epa.gov/otaq/regs/fuels/rfgforms.htm>, J. Craig Mazzolini, (406) 761-1825.
 - Biodiesel Fuel Registration for Ultra Low Sulfur Diesel Refinery with EPA, John Weihrauch, weihrauch.john@epa.gov, forms 3520-20A and 3520-20B1, <http://www.epa.gov/otaq/regs/fuels/rfgforms.htm>
 - Commodity Conservation Credit Program License/Eligibility (USDA)
 - One-Stop Licensing (for retail pumps & tanks, convenience stores, etc), Montana Department of Revenue)
 - Montana Biodiesel Production Credit: Montana Department of Transportation (MDT), Vanessa Olson, Fuel Tax Management and Analysis Bureau Section Supervisor, (406) 444-7276, volson@mt.gov
 - Oil Seed Crushing and Biodiesel Production Facility Credit: Montana Department of Revenue (DOR), Jim McKeon, Tax Specialist (406) 444-1940 jmckeon@mt.gov
 - Special Fuel Distributors License Tax: Montana Department of Transportation, (MDT)
 - Volumetric 'Blender' Tax Credit information from the Internal Revenue Service (IRS) (including Form 637, Form 720, Form 8849, Form 8864, and Form 4136 and others) are available at: <http://www.irs.gov/formspubs/lists/0,,id=97817,00.html> .

2. Considerations:

- Preliminary anecdotal data indicate that the use of camelina oil or use of biodiesel from unrefined camelina biodiesel produces varnish and deposits on interior engine parts. It cannot be determined that the biodiesel met ASTM D6751 specifications. Degumming and refining may be required before camelina oil could be used for fuel. Additional research and data development are needed in a systematic method to determine if these processes are required.
- Preliminary anecdotal reports indicate that camelina biodiesel may have superior cold climate characteristics, including cloud points of around -35 F. Specification-grade camelina biodiesel needs to be evaluated to make this determination.

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- Recently approved revisions to ASTM D6751 may have placed a penalty for increased oxidation on long-chain mono-alkyl esters such as those possibly present in camelina biodiesel. A “standard” camelina oil needs to be made into a certification-grade biodiesel and evaluated. If camelina biodiesel is not as oxidatively stable, production of select desirable fatty acids should be undertaken to increase oxidative stability to commercial-grade storage life.
- Waiver to use uncertified alternative fuels. This includes straight vegetable oil (SVO), and used cooking oil as fuel or E85, and any vehicle modification for use of any of these fuels. Straight vegetable oil as a fuel is not yet certified for use by the Environmental Protection Agency (EPA) under the Clean Air Act. Waivers can be obtained for research and demonstration. Contact: Martin Reinemann, EPA Fuels and Vehicle Emissions Center, Ann Arbor, MI, (734) 214-4430, reineman.martin@epa.gov.